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(54) A medical device for fluid delivery

(57) A method for predetermining the controlled and uniform discharge rate of a fluid from a single lumen tubular body having passageways radially extending through the wall of the tubular body has been developed and is described. The method involves predetermining such parameters as the transverse cross-sectional areas of the passageways extending through the wall of the tubular body, the spacing of the passageways, the pressure at each of the passageways, and the rate of flow at each of the passageways. One specific preferred application of such a tubular body is an infusion catheter for delivering various fluids to designated areas of the body for either a therapeutic treatment and/or diagnostic purposes. For example, such a catheter may be adapted to deliver controlled and uniform quantities of thrombolytic agents, chemotherapeutic agents as well as such diagnostic agents as fluorescent dies and radioactive agents.

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Description

The present invention relates to medical devices such as infusion catheters from which the delivery of fluid into a patient is controlled.

In certain medical conditions, it is advantageous to deliver a therapeutic agent directly to a target region to avoid medicating the entire body and to limit the amount of therapeutic agent required for effective treatment. Alternatively the same objective may be desirable for a diagnostic agent. One example of such a medical condition is an arterial thrombus, or clot, which can be treated effectively by localized application of such therapeutic fluids as those containing tissue plasminogen activator, urokinase, or streptokinase.

Infusion catheters have been developed which can deliver therapeutic fluids directly to affected bodily passages, for example a thrombotic region of an artery. One type of infusion catheter is a hollow tube, the distal end of which has been pierced through its side wall to form multiple openings, or ports, providing direct access to the exterior for fluid flowing through a common central lumen. The ports are disposed at several axial positions along the infusion section to provide distribution of the therapeutic fluid along a desired length of the bodily passage. However, fluids flowing through a tube flow more readily from ports offering the least flow resistance. The longer the flow path followed by the fluid in the central lumen, the higher the resistance and the higher the pressure drop (AP) in the fluid. If the infusion section of this catheter has multiple ports or passageways the fluid flowing from each port exhibits resistance and a AP proportional to the fluid flow distance along the length of the central lumen. Thus, the fluid flowing to the more distal ports experiences higher AP than that flowing to the more proximal ports, and the fluid distribution is not uniform.

With respect to delivering various agents to specific regions of the body, the wall of a normal blood vessel includes an endothelial surface layer with an underlying connective tissue layer. When the wall of a blood vessel is diseased or injured, the endothelial surface layer breaks or tears. The break or lesion in the endothelial surface layer exposes collagenous connective tissue fibers to the blood flowing through the lumen of the blood vessel. Platelets present in the bloodstream adhere to the collagenous fibers, thereby initiating the coagulation cascade that results in a clot. The clot projects radially from the vessel wall into the lumen of the blood vessel and may cause turbulent flow.

Intravenous thrombolytic therapy breaks apart clots and restores laminar flow through the blood vessel and into other areas of the vascular system. Typically, intra-arterial thrombolytic therapy is provided by placing an infusion catheter or wire guide within the clotted lesion of a blood vessel so that a thrombolytic agent is infused into the vessel lumen in the region of the clot.

Conventional techniques utilize catheters and wire guides with multiple sideports intended for increasing the volume of the thrombolytic agent flowing into the bloodstream. For example, some infusion catheter sets include coaxially positioned inner and outer catheters, each with a number of sideports or infusion slits. Another coaxial infusion set includes an outer catheter with sideports and an inner wire guide with infusion holes. Yet other multiple sideport infusion sets include a catheter with sideports and a wire guide for extending through the lumen of the catheter and occluding the distal end hole of the catheter.

A problem with these multiple sideport devices is that most or all of the thrombolytic agent is diffused through only one or two proximal sideports, thereby limiting the surface area of the targeted blood vessel which could be treated by the released thrombolytic agent. As a result, the thrombolytic agent does not adequately mix with blood throughout the lesion. The relatively low concentration of the thrombolytic agent in the blood is insufficient to provide the desired therapeutic effect before being carried away in the blood stream.

Furthermore, the uneven flow of the thrombolytic agent from the infusion sideports creates turbulence in the bloodstream. The turbulence can cause particles of the clot to fracture and flow farther along the arterial system into decreasing caliber blood vessels. Historically, treating tandem clots is more difficult and time consuming than the slow dissolution of one clot. Another difficulty encountered in treating a tandem clot is that the infusion device might not fit into the lumen of the blood vessel where the particle is wedged and occluding blood flow.

According to the present invention there is provided a device as defined in claim 1,2 or 3.

The present invention overcomes the aforementioned problems and relates to a medical device comprising a tubular body with a plurality of discharge ports in the wall of the body for delivering fluid to designated areas of a patient, the flow of fluid from each port being at a respective controlled rate. The invention further relates to a catheter that is capable of delivering a variety of fluids to the human body. The invention includes methods for precisely calculating the transverse cross-sectional area or areas of the fluid passageways which extend preferably radially through the side wall of a tubular body. When it is desired to have a constant flow of fluid from each of the passageways, with predetermined spacings between them, then the cross-sectional areas of the passageways will be different.

In accordance with one aspect of the present invention, a single lumen medical device for the uniform delivery rate of a fluid is provided wherein the device comprises:

a) an elongated tubular body having proximal and distal ends;

b) a plurality of longitudinally spaced fluid passageways which extend through a length of the sidewall of the elon-

gated tubular body, wherein at least one of the spacing of the passageways along the length of the tubular body the fluid flow rate out of the tubular body or the pressure of the fluid in the tubular body at each passageway is controlled; and the transverse cross-sectional areas of the passageways are predetermined to provide a controlled rate of discharge of fluid from each of the passageways, and

c) means at the proximal end of the tubular body for connection to fluid to be fed into the lumen of the device.

In accordance with another aspect of the present invention there is provided a medical device for providing controlled fluid flow, said device comprising:

a) an elongated tubular body having proximal and distal ends:
b) means at the proximal end of the tubular body to direct the fluid into the lumen; and
c) a plurality of longitudinally spaced fluid passageways which extend through the sidewall of the elongated tubular body and along the length of the sidewall, wherein the transverse cross sectional area of each passageway are predetermined to provide a controlled uniform rate of discharge of fluid from the tubular body, wherein when the spacing of the passageways is set at a constant value and the transverse cross sectional area of the passageways are predetermined by the method comprising:

i) means for determining the constant rate of flow Q_i out of each i^{th} passageway from the flow rate of the fluid into the lumen of the tubular body;
ii) means for determining the pressure P_i at the i^{th} passageway from the known pressure P_{amb} outside the tubular body:
iii) means for calculating the diameter D_i of each i^{th} passageway from the known viscosity μ of the fluid directed into the proximal end of the tubular body according to the following formula:

$$D_i = \left(\frac{3840\ \mu\ Q_i}{\pi (P_i - P_{amb})} \right)^{1/3}$$

is provided, and wherein when the spacing of the passageways is unequal, the formula is adapted to compensate for the unequal spacing, and/or passageway shape.

In accordance with a further aspect of the present invention, there is provided a catheter comprising:

i) an elongated tubular body having proximal and distal ends;
ii) a plurality of longitudinal spaced fluid passageways which extend through the sidewall of the elongated tubular body and along the length of the sidewall, wherein at least one of the spacings of the passsageways, the fluid flow rate from the tubular body or the pressure of the fluid in the tubular body at each of the passageways is predetermined, and the transverse cross sectional area of each of the passageways are precisely predetermined to provide a controlled rate of discharge of fluid from each passageway, and
iii) means at the proximal end of the tubular body for directing fluid into the lumen.

According to a further aspect of the present invention, there is provided a medical device comprising a flexible single lumen tubular body having proximal and distal ends, passageways formed in the wall of the tubular body along a length thereof, wherein the cross-sectional area of the passageways are predetermined according to the following formula:

$$D_i = \left(\frac{3840\ \mu\ Q_i}{\pi (P_i - P_{amb})} \right)^{1/3}$$

wherein D_i is the dimension of each i^{th} passageway, Q_i is the constant rate of flow of fluid discharged out of each i^{th} passageway, μ is the viscosity of the fluid directed into the proximal end of the tubular body, P_{amb} is the pressure outside the tubular body and P_i is the pressure at each i^{th} passageway, and wherein the spacing of the i^{th} passageway is set at a constant value. With unequal spacing between the passageways, the formula requires adaption to provide dimension information.

The medical device thus has fluid passageways formed in a section of the catheter, and the transverse cross sectional area of the passageways increases from the proximal end section to the distal end section of the device.

It is desirable, in order to provide a uniform flow of fluid from the passageways or ports, to have the ports substan-

tially equally spaced-along the catheter wall. In that way, the section of the patient requiring treatment, receives an even distribution of medication.

Distribution of fluid from ports, the ports being controllable by increasing the cross-sectional area of the ports as the distance of each respective port from the proximal end of the catheter is increased.

When it is desired to have the ports almost equally spaced from one another, the size of each port can be controlled so that a uniform rate of discharge of fluid can be achieved from each. A formula for calculating the size of each port is provided hereinafter. If there are to be variations from that uniformity of spacing, then equivalent formulae can easily be calculated by persons skilled in the art to provide the various port sizes to achieve the uniformity of flow. Such uniformity is only preferable and variations from the calculated port sizes would also fall within this invention.

Brief Description of the Drawing

The invention will be further described in connection with the attached drawing in which:

FIG. 1 is a perspective view of a medical device according to one embodiment of the present invention; and
FIG. 2 is a sectional view of the distal end of a medical device according to one embodiment of the present invention.

Detailed Description

An exemplary embodiment of the elongated tubular body according to the present invention is a single lumen infusion catheter. A method has been developed to predetermine a controlled rate of discharge from any particular outlet of a series of outlets of the catheter or from segments or sections of the catheter. This exemplary catheter is illustrated in FIG. I where infusion catheter 10 includes elongated tubular body 12 having a proximal end 16 and distal end 14. A fluid, e.g., a therapeutic or diagnostic agent, may be introduced into the single lumen 20 to be discharged into the body through fluid passageways 18 at a controlled and preferably at a uniform rate from each passageway. The catheter further comprises an elongated section 19 having no fluid passageways and further comprises a distal radiopaque tip 11 and a proximal radiopaque band 15 or marker to indicate the boundary of the section of the catheter containing the fluid passageways 18. The radiopaque tip 11 may be molded into the catheter body from a molding composition comprising about 80% tungsten by weight. However, any known method for producing a radiopaque tip may be employed. Likewise, the radiopaque band 15 is preferably a metal band and is most preferably a platinum/iridium (Pt/Ir) metal alloy band. As with the radiopaque tip 11, any known metal or means to render the proximal boundary radiopaque may be employed.

Depending upon the particular application and fluid agent being infused, the rate of fluid discharge may vary at designated sections along the length of the catheter but at a controlled rate within each designated section. One or more of the sections need only have one passageway, if required. Moreover a guidewire, not shown, may be contained within the lumen 20 for the insertion and advancement of the catheter 10.

For infusion catheters, it is highly desirable to deliver the particular fluid, whether a therapeutic agent or a diagnostic agent, to the particular area of the body for treatment or diagnosis and that the fluid be delivered at a controlled and preferably uniform rate of discharge. Not only is it important to control the rate of discharge of fluid to achieve the desired therapeutic effect or diagnostic result, but also to avoid or minimize damage to the body tissue by frictional or shear forces or by too high pressure or volume of fluid. To achieve the desired control and uniform rate of discharge of fluid from the passageways of the catheter, a method has been devised for predetermining the transverse cross-sectional area of the passageways, as well as the spacing of the passageways, the flow rate of the fluid discharged out of the passageways, and the fluid pressure at each of the passageways. By way of illustration only, a three-hole or three-passageway catheter is shown in FIG. 2. The portion of tubular body 12 containing passageways 18 and lumen 20 in which guidewire 22 is contained and creating space 21 into which a fluid is delivered. In order to predetermine the rate of fluid discharge 24, and further identified herein as Q_i from passageways 18 and their respective diameters or transverse cross-sectional areas 23A, 23B, 23C, the ambient pressure 26, given the designation and symbol P_{amb}, exterior to the catheter must be determined and the pressure P_i, 27A, 27B and 27C must also be determined. The spacing 25 of the passageways 18 is preferably set at a constant value.

The fluid in the catheter was assumed to have the properties of water at a temperature of 68° F (20°C). However, it is understood that the viscosity may vary with temperature and the appropriate values utilized to ensure uniform flow rates and laminar flow. The pressure and flow rate terms shown in Figure 2 are:

P_{amb} =	ambient pressure outside the catheter
P_1, P_2, P_3 =	pressure in the tube at the three holes
Q_t =	total flow rate through the catheter
	= 50 to 150 ml/hr

Q_0 = flow rate out of the end of the catheter
Q_1, Q_2, Q_3 = flow rates out of the three holes

The procedure used has three parts. The first step is to set the flow rates out of the side-holes 18 and the end-hole (not shown) as percentages of the total flow. The second step is to find the pressure in the tube at each hole. The last step is to find the size of the hole needed for the given flow. The second and third steps are repeated for each hole, starting with the hole closest to the end of the tube.

Since the flow rates out of the holes are desired to be equal and the flow rate out of the end should be small compared to the other flows, it is assumed, for the purposes of this illustration, that 30% of the total flow goes out of each hole and 10% out of the end.

To find the pressure at the inlet of the holes, some geometric data is needed. The first is the cross-sectional area of the annulus. It is:

$$A_c = \frac{\pi}{4}\left(D_0^2 - D_i^2 \right) \qquad (1)$$

where:

A_c = cross-sectional area of the annulus or fluid space 21

The wetted perimeter of annulus 21 is:

$$P_w = \pi (D_o + D_i) \qquad (2)$$

where:

P_w = wetted perimeter of the annulus 21

The following parameters chosen for the purposes of this illustration.

D_i = diameter of the guide wire 22 = inner diameter of the annulus 21
= 0.035"
D_0 = inner diameter of the lumen 20 = outer diameter of the annulus 21 and is for this example
= 0.048"
t = thickness of the tube
= 0.0095"
L_1 = distance from the center of the first hole to the end of the tube
= 1.57"
L_2 = distance from the center of the second hole to the center of the first hole
= 1.57"
L_3 = distance from the center of the third hole to the center of the second hole
= 1.57"
D_1, D_2, D_3 = diameters of the three holes 18

Equations (1) and (2) are valid even if the guidewire 22 is touching the tube wall since the area of contact is small. Even though the cross-section is not circular, it can be approximated as a circular cross-section with an effective diameter. This allows the use of equations derived for circular cross-sections. The effective diameter is called the hydraulic diameter and is defined as:

$$D_h = \frac{4\,A_c}{Pw} \qquad (3)$$

where:

D_h = hydraulic diameter

For an annular region, the hydraulic diameter reduces to the difference between the inner and the outer diameter.

Since the fluid velocity in the annulus is small and the changes in elevation are small, the equation for the pressure at the first hole is:

$$P_1 = P_{amb} + \frac{f\rho\, V_{a1}^2\, L_1}{2\, D_h} \tag{4}$$

where:

f = friction factor
ρ = density of the fluid
V_{a1} = average velocity of the fluid in the annulus through the distance L_1

The velocity in the annulus is:

$$V_{a1} = \frac{Q_{a1}}{A_c} \tag{5}$$

where:

Q_{a1} = flow rate in the annulus through the distance $L_1 = Q_0$

The Q_{a1} notation is used so that the same equations will be valid for other sections of the annulus.

The friction factor is a coefficient based on the flow conditions and the material of the tubing. Since the flow is laminar (as will be shown later), the friction factor is only a function of the flow conditions and is:

$$f = \frac{64}{Re_{a1}} \tag{6}$$

where:

Re_{a1} = Reynolds number in the annulus 21 through the distance L_1

The Reynolds number is a dimensionless number that describes the flow. It is defined as:

$$Re_{a1} = \frac{\rho\, V_{a1}\, D_h}{\mu} \tag{7}$$

where:

μ = viscosity of the fluid

Substituting equations (3) and (5) into equation (7) gives:

$$Re_{a1} = \frac{4\rho\, Q_{a1}}{\mu\, P_w} \tag{8}$$

Substituting equation (8) into equation (6) gives:

$$f = \frac{16\,\mu\,P_w}{\rho\,Q_{a1}} \tag{9}$$

Substituting equations (3), (5), and (9) into equation (4) gives:

$$\Delta P_1 = \frac{32\,\mu\,Q_{a1}\,L_1}{D_h^2\,A_c} \tag{10}$$

where:

ΔP_1 = change in pressure from the distal end of tube to hole 1

Using equation (10) the pressure difference between each hole can be found. In general, equation (10) is:

$$\Delta P_1 = \frac{32\,\mu\,Q_{a1}\,L_1}{D_h^2\,A_c} \tag{11}$$

where:

ΔP_1 = change in pressure from hole I-1 to hole I
Q_{ai} = flow rate in the annulus through the distance L_1
$= Q_0 + Q_1 + \ldots + Q_{i-1}$

The pressure at each hole is then:

$$P_i = P_{amb} + \Delta P_1 + \ldots + \Delta P_i \tag{12}$$

With the pressure known at each hole, the diameters can be calculated.

Several assumptions were made about the flow through the holes. The first is that the flow through the holes causes no pressure drop in the fluid in the annulus. The second is that the flow through the holes can be treated like flow through an elbow. The losses through an elbow can be approximated by the frictional losses through a length of tubing 30 diameters long. The change in pressure from one side of the hole to the other is:

$$P_1 - P_{amb} + \frac{f_i\,\rho\,V_i^2\,(30\,D_i)}{2\,D_i} \tag{13}$$

where:

V_i = velocity through hole I

The velocity through the hole is:

$$V_i = \frac{Q_i}{A_i} = \frac{4Q_i}{\pi\,D_i^2} \tag{14}$$

where:

A_i = cross-sectional area of hole I

Substituting equation (14) into equation (7) gives:

$$Re_i = \frac{4\rho Q_i}{\pi \mu D_i} \quad (15)$$

where:

Re_i = Reynolds number through hole I

Substituting equations (6), (14) and (15) into equation (13) gives:

$$P_i - P_{amb} = \frac{3840 \mu Q_i}{\pi D_i^3} \quad (16)$$

Solving equation (16) for D_i gives:

$$D_i = \left(\frac{3840 \mu Q_i}{\pi (P_i - P_{amb})} \right)^{1/3} \quad (17)$$

Equivalent formulae exist for fluid passageways of shapes other than circular, and can easily be calculated by one skilled in the art. This also applies to different spacings between the passageways.

Using equation (17), the diameters of the holes 18 may be found.

Example: Three hole catheter.

To demonstrate the procedure derived in the Analysis section, the case shown in Figure 2 will be analyzed. The total flow rate is 100 ml/hour or 9.809×10^{-7} ft^3/s. Ten percent of the flow goes out of the end and 30% goes out of each hole. From equation (1), the cross-sectional area of the annulus is:

$$A_c = \frac{\pi}{4}\left((0.048)^2 - (0.035)^2 \right) = 8.474 \times 10^{-4} \text{ in.} \quad (18)$$

From equation (2), the wetted perimeter is:

$$P_w = \pi(0.048 + 0.035) = 0.261 \text{ in.} \quad (19)$$

From equation (3), the hydraulic diameter is:

$$D_h = \frac{4 (8.474 \times 10^{-4})}{0.261} = 0.013 \text{ in.} \quad (20)$$

With the basic geometric information calculated, the pressures and diameters can be calculated. The fluid properties are needed first. For water at 68°F, the density is 62.5 lbm/ft^3 and the viscosity is 67.6×10^{-5} lbm/ft s. From equation (11), the pressure at hole 1 is:

$$P_1 - P_{amb} = \frac{32(12)^3 (67.6 \times 10\text{-}5)(9.809 \times 10^{-8})(1.57)}{(32.2)(0.013)^2 (8.474 \times 10^{-4})} = 1.248 \frac{lbf}{ft^2} \quad (21)$$

The 32.2 term in the denominator of equation (21) is the unit conversion factor g_c. The value of g_c is 32.2 ft lbm/lbf s^2. This term is present in most of the example equations. The diameter of hole 1, from equation (17), is:

(22)

$$D_1 = 12\left(\frac{3840(67.6 \times 10^{-5})(2.943 \times 10^{-7})}{\pi\,(1.248)(32.2)}\right)^{1/5} = 0.0219 \text{ in.}$$

We need to check to see if the flow is laminar in all of the regions to verify that the correct equations were used. Flow is laminar if the Reynolds number is less than 2300. From equation (8), the Reynolds number in the annulus through L_1 is:

$$Re_{a1} = \frac{4(62.5)(9.809 \times 10^{-8})(12)}{(67.6 \times 10^{-5})(0.261)} = 1.67 \qquad (23)$$

From equation (15), the Reynolds number through hole 1 is:

$$Re_1 = \frac{4(62.5)(2.943 \times 10^{-7})(12)}{\pi\,(67.6 \times 10^{-5})(0.0219)} = 18.98$$

The flow is very laminar out of hole 1 and through the annulus from hole 1 to the end of the tube.

Table 1 summarizes the calculations for the remaining two holes. It is noted that the Reynolds number is less than 2300 in all regions indicating laminar flow through these regions.

Table 1.

Summary of calculations for three hole catheter.			
Hole I	1	2	3
Q_i (ft^3/s)	2.943×10^{-7}	2.943×10^{-7}	2.943×10^{-7}
Q_{ai} (ft^3/s)	9.809×10^{-8}	3.924×10^{-7}	6.866×10^{-7}
L_i (in.)	1.57	1.58	1.57
ΔP_i (lbf/ft^2)	1.248	5.025	8.738
P_i-P_{amb} (lbf/ft^2)	1.248	6.273	15.011
D_i (in.)	0.0219	0.0128	0.0095
Re_{ai}	1.67	6.67	11.67
Re_i	18.98	32.51	43.49

While the foregoing examples illustrate specific embodiments according to the present invention, numerous variations of the catheters described above are considered to be within the scope of the invention. For example, the passageways for discharging the fluid may be arranged in a number of ways including linearly along the one side of the catheter, there may be for example, two opposing passageways 180° with respect to each passageway on either side of the catheter, there may be four passageways disposed within the same plane and arranged 90° with respect to each passageway and the like or in one preferred embodiment the passageways may be spiraled 90° along the length of the catheter. The passageways may be formed by several different techniques depending upon the materials out of which the catheter is formed as well as the particular application or use of the particular catheter. In one preferred embodiment, the fluid passageways are drilled with a laser, particularly in catheters where very small diameters or transverse cross-sectional areas are required. While the passageways are generally cylindrical in shape; they may have any geometric shape, e.g., conical, cubic and the like. Also, the catheter may be formed by known molding techniques, e.g., extrusion, or injection molding. Another consideration is that the catheter may have a varying wall thickness along it's length.

The catheter may be formed from conventional flexible materials. For example, such materials that may find application for preparing the catheters according to the present invention are polyethylene, polypropylene, polyethylene terephthalte, nylon, and various silicon based polymers. As a most preferred embodiment according to present invention, the catheter is prepared from nylon. Also, the exterior wall of the catheter may contain a hydrophilic coating, e. g., polyvinyl pyrrolidone, polyethylene glycol, polyethylene oxide, and the like, to improve the ease of inserting the catheter in the body of the patient.

The catheter according to present invention may be utilized, for example, to infuse such agents as chemotherapeutic agents, thrombolytic agents, antibiotics, or diagnostic agents, e.g., dyes and radioactive materials, or more inert fluids such as heparin, saline solution and the like. Moreover, the technique of predetermining the diameter and spacing of the fluid passageways may be employed in producing other elongated tubular bodies for use in industry and introducing fluids into a system, e.g. inert gases into a chemical reaction, fluid reactants into a chemical reaction system and the like.

Claims

1. A single lumen medical device comprising an elongated tubular body with proximal and distal ends, means for permitting fluid to be supplied to the body at or adjacent to the proximal end, and a plurality of ports extending through the sidewall of the body, wherein the cross sectional areas of the ports increases in size as the distance of respective ports from the proximal end also increases in size.

2. A single lumen medical device, comprising:

   a) an elongated tubular body having proximal and distal ends;
   (b) means at the proximal end of the tubular body for permitting fluid to enter into the lumen, and
   (c) a plurality of longitudinally spaced fluid passageways which extend through the sidewall of the elongated tubular body over a length or section of the sidewall, wherein at least one of the spacing of the passageways along the tubular body, the fluid flow rate out of the tubular body or the pressure of the fluid in the tubular body at each passageway is predetermined; and the transverse cross-sectional area or areas of the passageways and/or the distances between the passageways are precisely predetermined to control the rate of discharge of fluid from the passageways.

3. A medical device comprising an elongated tubular body, means adjacent the proximal end thereof to supply fluid to the body, and passageways through the wall of the body, wherein the transverse cross-sectional area of each passageway is determined according the the following formula:

$$D_i = \left(\frac{3840\ \mu\ Q_i}{\pi\ (P_i - P_{amb})} \right)^{1/3}$$

   wherein D_i is the diameter of each i^{th} passageway, Q_i is the constant rate of flow of fluid discharged out of each passageway, μ is the viscosity of the fluid directed into the proximal end of the tubular body, P_{amb} is the pressure outside the tubular body and P_i is the pressure at each i^{th} passageway and wherein the spacing of the i^{th} passageways is set at a constant value, or according to an equivalent formula adapted to compensate for unequal spacing between passageways, or to compensate for non-circular passageways.

4. The device according to claim 1 or 2, or 3, wherein said fluid is either a therapeutic agent, or a diagnostic agent.

5. The device according to claim 1 wherein the transverse cross-sectional shape of the fluid passageways is cylindrical, or conical, and/or the passageways are spiraled 90° along the length of the tubular body, or at least two passageways are located in a single cross-sectional plane of the tubular body.

6. The device according to claim 1,2, or 3, wherein the tubular body is segmented with respect to different fluid discharge rates, and wherein the discharge from the passageways within each segment is controlled and uniform.

7. The device according to claim 1,2 or 3, wherein said tubular body is of flexible material and wherein the distal tip of the tubular body is radiopaque and a radiopaque band is positioned at the proximal terminus of the fluid passageways in order to mark the boundaries of the section of the medical device containing said fluid passageways.

8. The device according to claim 7, wherein said flexible material is nylon and said proximal radiopaque band is comprised of Pt and Ir.

9. The device according to claim 1, 2 or 3, wherein the device is designed so that the flow of the fluid within the lumen of the tubular body is laminar, and/or wherein the wall thickness of the tubular body varies along the length of the tubular body and the exterior wall of the catheter comprises a hydrophilic coating, and/or the device contains a guide wire.

FIG. 1

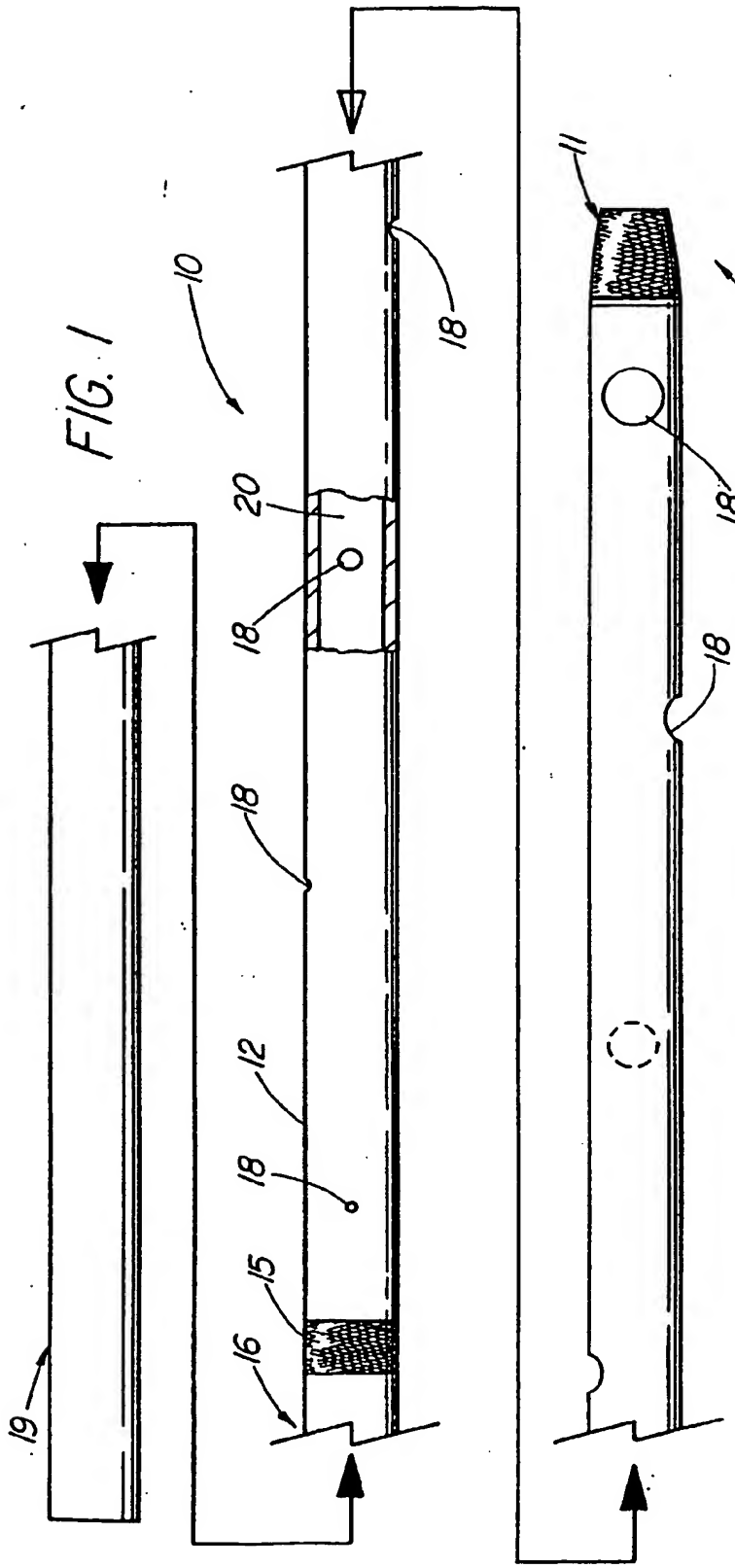
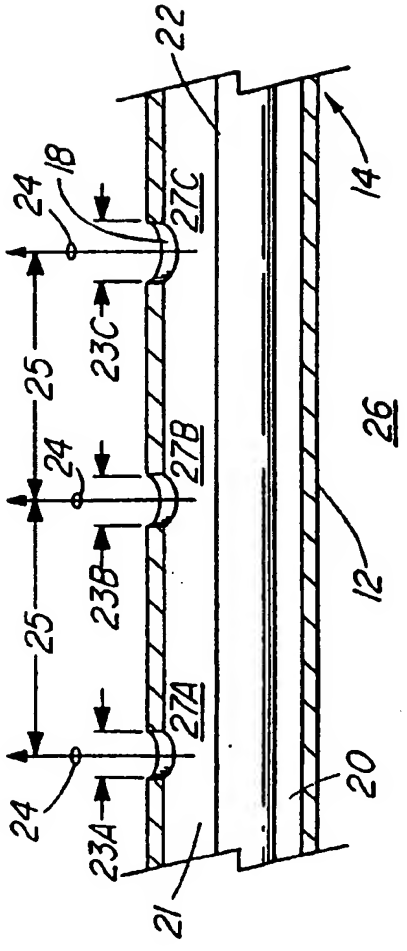


FIG. 2



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(54) A medical device for fluid delivery

(57) A method for predetermining the controlled and uniform discharge rate of a fluid from a single lumen tubular body having passageways radially extending through the wall of the tubular body has been developed and is described. The method involves predetermining such parameters as the transverse cross-sectional areas of the passageways extending through the wall of the tubular body, the spacing of the passageways, the pressure at each of the passageways, and the rate of flow at each of the passageways. One specific preferred application of such a tubular body is an infusion catheter for delivering various fluids to designated areas of the body for either a therapeutic treatment and/or diagnostic purposes. For example, such a catheter may be adapted to deliver controlled and uniform quantities of thrombolytic agents, chemotherapeutic agents as well as such diagnostic agents as fluorescent dies and radioactive agents.

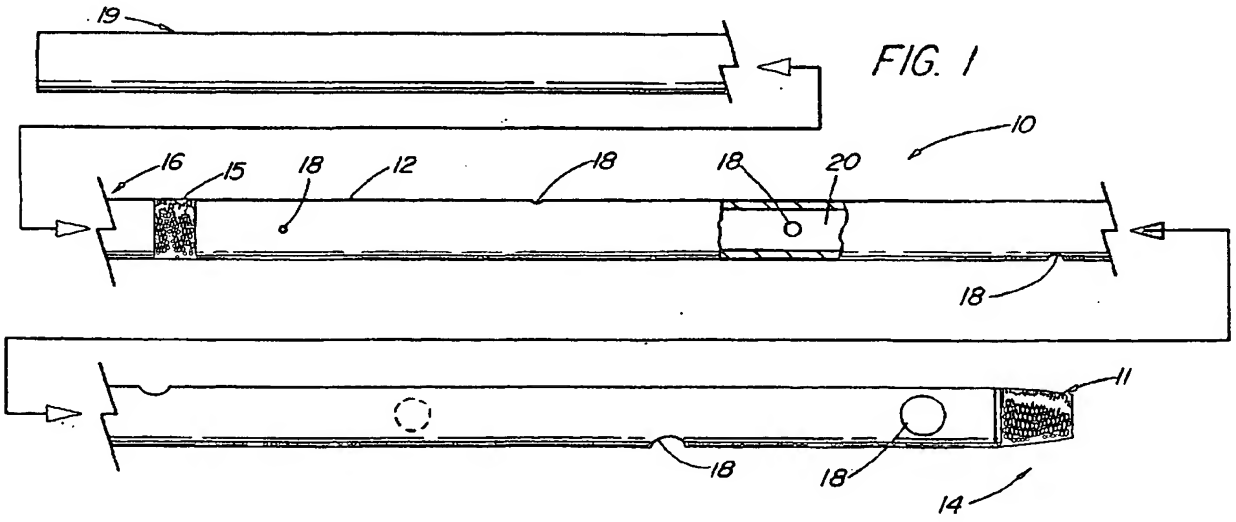

FIG. 1

EP 0 804 936 A3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 30 2755

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	WO 94 07549 A (TARGET THERAPEUTICS INC) * page 6, line 6 - line 28; figures *	1-9	A61M25/00
X	US 4 173 981 A (MORTENSEN) * column 3, line 48 - column 4, line 13; figures *	1-9	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	17 December 1997	Clarkson, P

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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E : earlier patent document, but published on, or after the filing date
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